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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,155	03/01/2004	Arnon Lavie	02-134-D	3822

7590 06/21/2005

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EXAMINER	
YAO, LEI	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,155	LAVIE ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-169* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-169* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16 and 69, drawn to an antibody-conjugated enzyme, classified in class 530, subclass 391.1.

II. Claims 17-34, drawn to a method of reducing, inhibiting, or preventing proliferation of tumor cell comprising the step of contacting the tumor cell in the presence of a prodrug with antibody-enzyme conjugate, classified in class 435, subclass 7.1 and 7.23.

III. Claims 35-53, drawn to a method of reducing drug-resistance in a cancer patient comprising administering the antibody-conjugated enzyme to patient, classified in class 424, subclass 178.1.

IV. Claims 54-68, 70-84, 105-124, drawn to a method of treating a cancer patient comprising administering the antibody-conjugated enzyme and a chemotherapeutic agent to a patient, classified in class 424, subclass 178.1.

V. Claim 85-104, drawn to a method of increasing the efficacy of a chemotherapeutic agent in a cancer comprising administering the antibody conjugated enzyme, wherein the enzyme activated the chemotherapeutic agent, classified in class 424, subclass 178.1.

VI. Claims 125-144, drawn to a method of overcoming chemotherapeutic drug resistance in a cancer patient comprising administering the antibody-conjugated enzyme and a chemotherapeutic agent to a patient, classified in class 424, subclass 178.1.

VII. Claims, drawn to 145-164, drawn to a method of overcoming chemotherapeutic drug resistance in tumor cell, comprising contacting tumor cell with the antibody-conjugated enzyme, classified in class 435, subclass 7.1 and 7.23.

VIII. Claims 165-168, drawn to an isolated polynucleotide encoding the modified deoxycytidine kinase, a host cells, and a method of making the kinase, classified in class 536, subclass 23.1 and class 435, subclass 69.1.

IX. Claim 169, drawn to a method of purifying the antagonist for deoxycytidine kinase from the host cell culture, unclassified.

Inventions Group I and Groups II, III, IV, V, VI, or VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The product as claimed in group I can be used in a materially different process of inventions of II, III, IV, V, VI or VII.

Searching the inventions of Group I and II, III, IV, V, VI, or VII together would impose serious search burden. The inventions of I and II, III, IV, V, VI, or VII have a separate status in the art as shown by their different classifications.

Invention II, III, IV, V, VI, or VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II, III, IV, V, VI, or VII are unrelated methods because each invention requires different patient population or biological samples from different patients. Each method also has different modes of operation and different treatment effect. Invention III is a method of reducing drug-resistance in a cancer patient by administering the antibody-enzyme conjugate, it requires patients, who are previously treated with chemotherapeutic agent or have a chemoresistant cancer. Invention IV is a method of treating a cancer patient with the antibody-enzyme conjugate plus chemotherapeutic agent. It needs different population of cancer patients. Invention V is in vivo method of increasing efficacy of chemotherapeutic agent in cancer patient, the method requires different mode of operation and the treatment may have different effects. Invention VI is in vivo method of overcoming chemotherapeutic drug resistance. The method may need the cancer patients, who have been previously treated with different chemotherapeutic agent from the drug used in the instant invention. Invention II or VII are in vitro method of inhibiting proliferation of tumor cells or overcoming

chemotherapeutic drug resistance in tumor cells. Each method required specific cell line or cell samples from different cancer patients.

Invention I of antibody-conjugated enzyme and invention VIII of isolated polynucleotide are patentably distinct products.

Claim IX is a method of purifying the antagonist for deoxycytidine kinase, which is a patentably distinct method from the invention II, III, IV, V, VI, or VII.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, Therefore, restriction for examination purposes as indicated is proper.

Election of species

This application contains claims directed to the following patentably distinct species of the claimed invention:

A. SEQ ID NO: 1 or SEQ ID NO: 5
B. Prostate, colon, ovarian, breast, leukemia cancer (or a corresponding cancer cell).
C. An antibody for CD33, antibody for CC49, HuM195, Herceptin.
D. A Nucleoside analog listed in specification (page 35).

In the event that applicant elects an invention from I –IX, applicant is required under 35 U.S.C. 121 to elect **a single disclosed species** from A, B, C and/or D, which is within the elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Dowining for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
6/16/05